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UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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02/057,017 05/05/99 KOUTZON

D US95-210-USA

H42270505

MICHAEL R. WARD  
LIMBACH & LIMBACH  
2001 PERRY BUILDING  
SAN FRANCISCO CA 94117

EXAMINER

WASHED, N

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Docket: 15611-7032  
Action: Response  
Date Due: 4/8/01  
Critical Date: 11/8/01  
Docketed By: RM  
Attorney App.: Jm  
Filed By:  
McCUTCHEN, DOYLE, BROWN & ENERSEN, LLP

# Office Action Summary

Application No.

09/367,013

Applicant(s)

Knutzon et al.

Examiner

Nashaat T. Nashed

Art Unit

1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 5, 1999
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 65-188 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 65-188 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I Claims 65-66, 93, 94, 99, 100 and 187, drawn to methods for making oleic acids, linolenic acid,  $\gamma$ -linolenic acid, stearidonic acid, and  $\alpha$ -linolenic acid.
- II Claims 67, 69-72, 91, 100, 102-105, 126, 129, 131-134, 153, 153, 156, 158-161, 180, 185, 186, and 188, drawn to microbial oil and pharmaceutical compositions.
- III Claims 97 and 98, drawn to methods for making  $\gamma$ -linolenic acid from linolenic acid.
- IV Claims 73-75, 106-108, 135-137, and 162-164, drawn nutritional composition.
- V Claims 76-78, 110, 111, 138-140, and 165-167, drawn to an infant formula.
- VI Claims 79-86, 112-119, 142-148, and 168-175, drawn to a dietary supplement and substitute.
- VII Claims 68, 87-88, 101, 121-123, 130, 149, 157, 176, and 177, drawn to a method of treatment.
- VIII Claims 89, 90, 124, 125, 151, 152, 178, and 179, drawn to a cosmetic composition.
- IX Claims 92, 127, 154, and 181, drawn to an animal feed.
- X Claims 95 and 96, drawn to the polypeptides of SEQ ID NO's: 34-40.
- XI Claim 182, drawn to nucleic acid sequences of SEQ ID NO's: 19, 21, 23, and 25.
- XII Claim 183, drawn to the polypeptides of SEQ ID NO's: 20, 22, 24, and 26.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of the invention of Group I is the transformed cell which is capable of making any of a fatty acid selected from the group consisting of oleic acids, linolenic acid,  $\gamma$ -linolenic acid, stearidonic acid, and  $\alpha$ -linolenic acid. Similarly, the special technical feature of the invention of Group III is the microorganism which converts  $\gamma$ -linolenic acid to linolenic acid. The microorganism of used in the method of Group I is different from that of Group II because the two microorganisms produces different products. The inventions of Groups II and IV-IX are drawn to a method of use and compositions of well known chemical

compounds which are not the contribution of the applicants, and thus, lack unity of invention with Groups I and II. The inventions of Groups X-XII are drawn to independent chemical compounds having different chemical structure, and therefore lack unity of invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- (1) Groups I, II, and IV-IX contains the following species: oleic acids, linolenic acid,  $\gamma$ -linolenic acid, stearidonic acid, and  $\alpha$ -linolenic acid;
- (2) Group X contains the following species: SEQ ID NO's: 34-40;
- (3) Group XI contains the following species: SEQ ID NO's: 19, 21, 23, and 25; and
- (4) Group XII contains the following species: SEQ ID NO's: 20, 22, 24, and 26.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: no claim is drawn to a single species.

The following claim(s) are generic: 65-96, and 99-188.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The invention of Group I is drawn to a method of making oleic acids, linolenic acid,  $\gamma$ -linolenic acid, stearidonic acid, and  $\alpha$ -linolenic acid. As indicated above, the special technical feature of this invention is a transformed microorganism. Although the five microorganisms used in making the different fatty acid may be transformed with one or more gene having the same function(s), each of the five microorganisms must have a unique gene that drive the carbon source toward the desired fatty acid and therefore, the five microorganism lack unity of

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invention. The inventions of Groups II, and IV-IX are drawn to different compositions and method of use of well known chemical compounds. They are oleic acids, linolenic acid,  $\gamma$ -linolenic acid, stearidonic acid, and  $\alpha$ -linolenic acid. The inventions of Group X and XII are drawn to different desaturases isolated from various biological source having different structure and function and therefore lack unity of inventions. Similarly, the nucleic acid of Group XI are isolated from different biological sources and encode different desaturases having different function and structure.

A telephone call was made to Michael Ward on March 15, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday-Thursday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Nashaat T. Nashed, Ph. D.  
Primary Examiner